IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE ABBOTT LABORATORIES NORVIR ANTI-TRUST LITIGATION

No. C 04-1511 CW

(Consolidated Case)
No. C 04-4203 CW

ORDER DENYING DEFENDANT'S RENEWED MOTION FOR SUMMARY JUDGMENT

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Defendant Abbott Laboratories moves for summary judgment. Plaintiffs John Doe 1, John Doe 2, and the Service Employees International Union Health and Welfare Fund (SEIU) oppose the motion. The matter was heard on April 7, 2006. Having considered the parties' papers, the evidence cited therein and oral arguments, the Court denies Defendant's renewed summary judgment motion.

BACKGROUND

Protease inhibitors (PIs) are considered the most potent class of drugs to combat the HIV virus. In 1996, Defendant introduced Norvir as a stand-alone PI with a daily recommended dose of 1,200

milligrams (twelve 100-mg capsules a day), priced at approximately eighteen dollars per day. Norvir is the brand name for a patented compound called ritonavir.

After Norvir's release, it was discovered that, when used in small quantities with another PI, Norvir would "boost" the anti-viral properties of that PI. Not only did a small dose of Norvir, about 100 to 400 milligrams per day, make other PIs more effective and decrease side effects associated with high doses, but it also slowed down the rate at which HIV developed resistance to the effects of PIs. The use of Norvir as a "booster" has enabled HIV patients to live longer. But the use of Norvir as a booster, and not a stand-alone PI, has also meant that the average daily price of Norvir has plummeted since Norvir was first introduced, because patients need only a small daily dose of Norvir as a booster. By 2003, the average daily price of Norvir was $1.71.

In 2000, Defendant introduced Kaletra, a pill containing the protease inhibitor lopinavir and Norvir. Although effective and widely used, Kaletra had significant side effects for some patients.

In 2003, two new PIs, Bristol-Myers Squibb's Reyataz and GlaxoSmithKline's Lexiva, were about to be introduced to the market. Studies showed that, when boosted with Norvir, the new PIs were as effective as Kaletra, and were more convenient. In July, 2003, Reyataz was successfully introduced to the market. As a result, Kaletra's market share fell more than Defendant anticipated. The average daily dose of Norvir also fell. Before Reyataz's release, the most common boosting dose of Norvir ranged

from 200 milligrams to 400 milligrams a day. Clinical trials, however, showed that a Norvir dose of only 100 milligrams a day effectively boosted Reyataz.

On December 3, 2003, Defendant raised by 400 percent the wholesale price of Norvir. Defendant contends that it raised Norvir's price so that it would be more in line with the drug's enormous clinical value. Plaintiffs contend that the Norvir price increase was an illegal attempt to achieve an anti-competitive purpose in the "boosted market," which Plaintiffs define as the market for those PIs, such as Reyataz, Lexiva and Kaletra, that are prescribed for use with Norvir as a booster. Plaintiffs sued for violations of section 2 of the Sherman Act and California Business and Professions Code section 17200.

On June 1, 2005, Defendant filed a motion for summary judgment. On June 27, 2005, Plaintiffs filed a Rule 56(f) response. The Court granted Plaintiffs' Rule 56(f) motion and denied Defendant's motion for summary judgment without prejudice as premature. Following further discovery, Defendant now renews its motion for summary judgment.

LEGAL STANDARD

Summary judgment is properly granted when no genuine and disputed issues of material fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Eisenberg v. Ins. Co. of N. Am., 815 F.2d 1285, 1288-89 (9th Cir. 1987).

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The court must draw all reasonable inferences in favor of the party against whom summary judgment is sought. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Intel Corp. v. Hartford Accident & Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

Where the moving party does not bear the burden of proof on an issue at trial, the moving party may discharge its burden of production by either of two methods. Nissan Fire & Marine Ins. Co., Ltd., v. Fritz Cos., Inc., 210 F.3d 1099, 1106 (9th Cir. 2000).

> The moving party may produce evidence negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may show that the nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial.

Id.

If the moving party discharges its burden by showing an absence of evidence to support an essential element of a claim or defense, it is not required to produce evidence showing the absence

of a material fact on such issues, or to support its motion with evidence negating the non-moving party's claim. Id.; see also Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 885 (1990); Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1409 (9th Cir. 1991). If the moving party shows an absence of evidence to support the non-moving party's case, the burden then shifts to the non-moving party to produce "specific evidence, through affidavits or admissible discovery material, to show that the dispute exists." Bhan, 929 F.2d at 1409.

If the moving party discharges its burden by negating an essential element of the non-moving party's claim or defense, it must produce affirmative evidence of such negation. Nissan, 210 F.3d at 1105. If the moving party produces such evidence, the burden then shifts to the non-moving party to produce specific evidence to show that a dispute of material fact exists. Id.

If the moving party does not meet its initial burden of production by either method, the non-moving party is under no obligation to offer any evidence in support of its opposition. Id. This is true even though the non-moving party bears the ultimate burden of persuasion at trial. Id. at 1107.

Where the moving party bears the burden of proof on an issue at trial, it must, in order to discharge its burden of showing that no genuine issue of material fact remains, make a prima facie showing in support of its position on that issue. UA Local 343 v. Nor-Cal Plumbing, Inc., 48 F.3d 1465, 1471 (9th Cir. 1994). That is, the moving party must present evidence that, if uncontroverted at trial, would entitle it to prevail on that issue. Id.; see also

Int'l Shortstop, Inc. v. Rally's, Inc., 939 F.2d 1257, 1264-65 (5th Cir. 1991). Once it has done so, the non-moving party must set forth specific facts controverting the moving party's prima facie case. UA Local 343, 48 F.3d at 1471. The non-moving party's "burden of contradicting [the moving party's] evidence is not negligible." Id. This standard does not change merely because resolution of the relevant issue is "highly fact specific." Id.

DISCUSSION

I. Plaintiffs' Claims under the Sherman Act

Defendant argues that Plaintiffs cannot satisfy the necessary elements of their monopolization or attempted monopolization claims under the Sherman Act. Specifically, Defendant argues that Plaintiffs' claims fail as a matter of law because (1) Kaletra's falling market share establishes a lack of monopoly power, (2) Plaintiffs cannot establish anti-competitive conduct, (3) Plaintiffs cannot establish an anti-trust injury and (4) Defendant's patents, which it contends cover the boosted market, provide immunity from Plaintiffs' anti-trust claims.

A monopolization claim under section 2 of the Sherman Act requires a plaintiff to prove "(1) possession of monopoly power in the relevant market, (2) willful acquisition or maintenance of that power, and (3) causal 'antitrust injury." Rutman Wine Co. v. E. & J. Gallo Winery, 829 F.2d 729, 736 (9th Cir. 1987). An attempted monopolization claim requires "(1) specific intent to control prices or destroy competition in the relevant market, (2) predatory or anti-competitive conduct directed to accomplishing the unlawful purpose, and (3) a dangerous probability of success."

Id. As the Ninth Circuit has noted, the requirements of both claims are similar, "differing primarily in the requisite intent and the necessary level of monopoly power." Image Technical Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1202 (9th Cir. 1997).

A. Monopoly Power

Monopoly power can be shown through either direct or circumstantial evidence. See Rebel Oil Co., Inc. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995). Plaintiffs contend that they have proferred both kinds of evidence that Defendant has monopoly power in the boosted market.

1. Direct Evidence

Plaintiffs present evidence showing that Defendant's 400 percent increase of Norvir's price had a significant impact on the boosted market. One of Defendant's competitors in the boosted market, GlaxoSmithKline, the maker of Lexiva, believed that Lexiva's failure to meet forecasted expectations was due, in part, to the Norvir price hike. Professor Douglas F. Greer, Plaintiffs' expert, notes that, in the absence of the price hike, Defendant anticipated that Kaletra's market share would decline by ten percent in 2004. But, according to Professor Greer, following the price increase in December, 2003, sales of Kaletra essentially remained stable. Furthermore, Defendant's documents show that it knew that raising Norvir's price could result in formularies restricting access to Norvir and a potential increase in Kaletra's market share. As a result of increasing the price of Norvir, Defendant believed that at least one of its competitors in the

boosted market "will need to give away significant rebates to be cost neutral to Kaletra."

Defendant responds that this is not direct evidence of monopoly power. Defendant contends that direct evidence requires proof that it restricted output to produce "supracompetitive prices." The case Defendant cites, however, involved predatory pricing, which is not at issue in this case. See Rebel Oil., 51 F.3d at 1434. As the court stated in Forsyth v. Humana, Inc., 114 F.3d 1467, 1475 (9th Cir. 1997), "Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices." But it does not have to be shown by such evidence. It can also be shown by "'injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power.'" Id. (quoting Rebel Oil., 51 F.3d at 1434). Plaintiffs provide such direct proof, thus creating a material factual dispute. See Confederated Tribes of Siletz Indians of Or. v. Weyerhaeuser Co., 411 F.3d 1030, 1043 (9th Cir. 2005) (defendant's employees' testimony that the defendant had power to influence prices and used that power was direct evidence).

2. Circumstantial Evidence

To demonstrate monopoly power by circumstantial evidence, Plaintiffs must "(1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry." Rebel Oil, 51 F.3d at 1434.

The relevant market is the boosted market. Both parties agree that, to establish a prima facie case of market power, courts

generally require a sixty-five percent market share. See, e.g., Image Technical, 125 F.3d at 1206. Professor Greer finds that Defendant's share of the boosted market is no longer falling and presently is seventy-three percent. Defendant attacks this figure: its vice-president contends that its share in the boosted market has fallen from seventy-seven percent in July, 2003, to forty-seven percent in November, 2005, well below the required sixty-five percent. In calculating Defendant's market share in the boosted market, Professor Greer contends that both of Defendant's products in that market must be accounted for: Kaletra and Norvir. The Court cannot determine, on a motion for summary judgment, who is providing the correct market share percentage, Plaintiff's expert economist or Defendant's vice-president; that must be determined by a jury.

Finally, circumstantial evidence of monopoly power also requires a showing that there are significant barriers to entry into the relevant market. Plaintiffs note that the cost of bringing a new PI to the market exceeds $300 million dollars and takes several years. It took GlaxoSmithKline over seven years to bring its PI, Lexiva, to the market. In addition, patents are a common entry barrier. Id. at 1208.

Defendant responds that there are no significant barriers, noting that two PIs created by its competitor are currently being evaluated in clinical trials. Defendant further notes that it costs hundreds of millions of dollars for any company to bring a new PI to the market; the fact that entry requires an enormous expenditure of funds does not by itself constitute a barrier to

entry. Los Angeles Land Co. v. Brunswick Corp., 6 F.3d 1422, 1428 (9th Cir. 1993). The hundreds of millions of dollars required, combined with the patents already in the field and the years required to get a product to the market, however, create a material factual dispute whether there are significant barriers to entry into the boosted market.

B. Anti-competitive Conduct

Defendant contends that, in order to offer evidence of anti-competitive conduct, Plaintiffs must show that Defendant impaired the opportunities of its rivals in an unnecessarily restrictive way. See Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585 (1985). That is incorrect. Aspen Skiing Co., involving a defendant's refusal to cooperate with its smaller rival, is inapposite. This is not a failure to deal, or failure to cooperate, case. Nor is this a case seeking liability under the Sherman Act for a defendant merely "charging too much." As this Court has recognized in its prior orders, Plaintiffs allege, relying on the monopoly leveraging theory recognized in Image Technical, 125 F.3d at 1208, that, while Defendant holds patents in the booster market, Defendant's Norvir price increase constituted impermissible anti-competitive conduct in the boosted market. See Image Technical, 125 F.3d at 1216 ("a monopolist who acquires a dominant position in one market through patents and copyrights may violate § 2 if the monopolist exploits that dominant position to enhance a monopoly in another market").

Plaintiffs provide evidence that Defendant abused its patent rights to Norvir to maintain its monopoly in the boosted market.

According to Plaintiffs' expert, although the 400 percent price increase did not raise Kaletra's market share, it raised its market share substantially above what it would have been absent the price increase. Even Defendant's calculations show that Kaletra remains the most prescribed PI in the boosted market. Defendant realized that drastically increasing the price of Norvir had the potential to increase Kaletra's market share in the boosted market; that potential was listed among the "pros" for raising Norvir's price.

Defendant offers evidence that its competitors are thriving. Defendant's data shows that, from July, 2003 to November, 2005, Reyataz's market share increased from 5.7 percent to 33.8 percent; Lexiva has achieved a 11.6 percent market share since it entered the market in November, 2004. Defendant notes that two of its competitors have raised the price of their PIs since it raised Norvir's price: GlaxoSmithKline twice raised Lexiva's price by a total of about ten percent and Bristol-Myers twice raised Reyataz's price by a total of about eight percent. Although this evidence may weaken Plaintiffs' case, it does not dispel the material factual dispute regarding whether Defendant engaged in anti-competitive conduct when it raised Norvir's price by 400 percent.

C. Anti-trust Injury

To show an anti-trust injury, Plaintiffs must prove that their loss flows from an anti-competitive aspect or effect of Defendant's behavior. See, e.g., Rebel Oil, 51 F.3d at 1433 (noting that "it is inimical to the antitrust laws to award damages for losses stemming from acts that do not hurt competition"). Defendant argues that Plaintiffs fail to show an anti-trust injury because

paying a high price for a patented drug is not an anti-trust injury. However, Plaintiffs provide their expert's finding that Defendant's price increase harms HIV patients by creating another barrier to entry that hinders the introduction of new PIs from Defendant's competitors, and, therefore, provide evidence of anti-trust injury.

Because there are disputed issues of material fact, the Court denies Defendant's motion for summary judgment that Plaintiffs have failed to establish a lack of monopoly power, anti-competitive conduct or anti-trust injury.

D. Asserted Anti-trust Immunity Based on Defendant's Patents

Defendant asserts that, even if it were capable of monopolizing the boosted market, its patent defense still ends this case in its favor. See Image Technical, 125 F.3d at 1215 ("Legally, a patent amounts to a permissible monopoly over the protected work."). Defendant argues that its patents cover the boosted market, as well as the booster market, and that, even if its patents do not cover boosted market, its decision to raise Norvir's price was not a pretext to monopolize the market.[1] Plaintiffs disagree, noting that Defendant bears the burden of establishing its patent immunity affirmative defense. See ITSI

[1] Defendant argues that, under Image Technical, it is entitled to summary judgment because there is no evidence of any anti-competitive intent that would rebut the presumption that its conduct was legitimate. See 125 F.3d at 1218-19. Defendant presents evidence that its decision to raise Norvir's price was a legitimate business decision. But Plaintiffs present evidence of anti-competitive intent, suggesting that Defendant's "legitimate business decision" was a pretext to monopolize, or attempt to monopolize, the market. Thus, summary judgment on this issue is not appropriate.

T.V. Productions, Inc. v. Agric. Associations, 3 F.3d 1289, 1291 (9th Cir. 1993) (an affirmative defense must be proved by the party that asserts it). According to Plaintiffs, Defendant fails to carry its burden because Defendant impliedly licensed patients to use Norvir as a booster and because its U.S. Patent No. 6,037,157 (the '157 patent) is invalid and its prosecution history shows that it does not encompass the use of Norvir with other PIs to treat HIV.

1. Defendant's Patents and the Boosted Market

Defendant notes that in Image Technology the defendant had patent rights over only one of the relevant markets; the plaintiffs alleged that the defendant's refusal to sell a patented product, the photocopier parts, was an attempt to monopolize an unpatented service market for repairing photocopiers. Defendant contends that, unlike the defendant in Image Technology, it has patents that cover both booster and boosted markets. Although Defendant states that it has at least two patents, the '157 patent and U.S. Patent No. 5,886,036 (the '036 patent), that plainly cover the boosted market, in the argument section of its moving papers, it focuses only on the '157 patent.

According to Defendant, the '157 patent claims a "method for improving" the efficacy of another protease inhibitor by administering a "therapeutically effective amount of a combination of said drug" and Norvir, and thus covers the boosted market. But, as Plaintiffs note, in proffering its proposed claim construction of the '157 patent, Defendant only paraphrases claim 1, which provides,

> A method for improving the pharmacokinetics of a drug which is metabolized by cytochrome P450 monooxygenase comprising administering to a human in need of such treatment a therapeutically effective amount of a combination of said drug or a pharmaceutically acceptable salt thereof and ritonavir or a pharmaceutically acceptable salt thereof.

Park Dec., Ex. C at 13:42-48.

The Federal Circuit has held that a patent's "prosecution history must be considered in construing claims." Pall Corp. v. PTI Techs., Inc., 259 F.3d 1383, 1391 (Fed. Cir. 2001), vacated and remanded on other grounds, 535 U.S. 1109 (2002). As the court explained in Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570 (Fed. Cir. 1995),

> Arguments and amendments made during the prosecution of a patent application and other aspects of the prosecution history, as well as the specification and other claims, must be examined to determine the meaning of terms in the claims. The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution. Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.

54 F.3d at 1576 (citations omitted).

The patent examiner twice rejected the '157 patent for obviousness. First, the examiner found that it would have been obvious to one skilled in the art to combine Norvir "with other HIV protease inhibitors for treating an HIV infection" because another of Defendant's patents, U.S. Patent No. 5,552,558 (the '558 patent), suggests this. Second Weibe Dec., Ex. D at 2. Defendant did not dispute this. Instead, Defendant asserted that the '558 patent "neither discloses or suggests (1) that ritonavir inhibits cytochrome P450 monooxygenase or (2) that ritonavir improves the pharmacokinetics of compounds which are metabolized by cytochrome

P450 monooxygenase" and therefore the '558 patent "does not make unpatentable the presently claimed invention." Id., Ex. E at 1-2. The patent examiner disagreed and for the second time rejected the '157 patent as obvious, stating that "one skilled in the art would have been motivated to use the combination of Ritonavir and another HIV protease inhibitor for treating an HIV infection since the utility is the same, i.e., increase efficacy of combination treatment and [the '558 patent] teaches using combination treatment for an HIV infection." Id., Ex. I at 2. Again, Defendant did not dispute this and instead focused on cytochrome P450 monooxygenase. In addition, Defendant amended its '157 patent application to cancel its express claims of use of Norvir with other PIs to treat HIV, although Defendant later refiled those canceled claims as a separate patent. Plaintiffs contend that, because Defendant did not argue during the patent prosecution that the patent covered Norvir's use as a booster, it should now be excluded from arguing that it does. See Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452-53 (Fed. Cir. 1985) (noting that "the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance").

Defendant responds that the '157 patent clearly covers the boosted market, arguing that the scope of a claim can be limited through disclaimer only where such a disclaimer is clear and unmistakable, determined by what "a competitor would reasonably believe that the applicant had surrendered." Tech. Licensing Corp. V. AV Techs. LLC, 2005 U.S. Dist. LEXIS 40717, *26 (E.D. Cal.

2005). Because five of its competitors took a license to the '157 patent, Defendant argues that its competitors do not believe that it disclaimed coverage over PI boosting. That argument is not convincing. Those competitors could have decided it was to their advantage to get a license, even while believing that Defendant did make a clear disclaimer. Defendant notes that most PIs are metabolized by cytochrome P450 monooxygenase. It could well be that the competitors whose PIs are metabolized by cytochrome P450 monooxygenase are the five who obtained a license. Defendant also argues that it did not disclaim Norvir's boosting use with other PIs because it later obtained a patent based on the cancelled claims of the '157 patent. This argument is likewise not convincing. In light of the prosecution history of the '157 patent, the Court is persuaded that Defendant disclaimed the use of Norvir with other PIs to treat HIV.

Nor is the Court persuaded that Defendant is entitled to immunity provided by its other patents that cover the boosted market. Defendant has the burden regarding its affirmative defense. It not meet its burden by referring to a case where another court found that it had patents covering Norvir's use in both the booster and boosted market. See Schor v. Abbott Labs., 378 F. Supp. 2d 850, 859 (N.D. Ill. 2005). In that case, unlike in this case, the plaintiff did not challenge Defendant's assertion that its patents explicitly cover the use of Norvir as a booster in combination with another PI. Defendant must do more than name a few of its patents, quote a couple of lines from each patent, and assert that each patent clearly covers the boosted market. Thus,

the Court denies Defendant summary judgment that its patents cover the boosted market. This issue remains in dispute.

2. Implied License

Plaintiffs contend that, even if Defendant's patents covered the boosted market, those patents would not give Defendant the power to exclude competitors from the boosted market because Defendant impliedly licenses patients to use Norvir as a booster. If patients are not potential or actual infringers, Plaintiffs contend that Defendant's competitors are not infringers. Thus, Defendant cannot sell Norvir for boosting use and then exclude competitors from the boosted market.

An implied license signifies a patentee's waiver of the statutory right to exclude others from making, using or selling the patented invention. Wang Labs., Inc. v. Mitsubishi Electronics Am., Inc., 103 F.3d 1571, 1580 (Fed. Cir. 1997). Implied licenses arise by acquiescence, by conduct, by equitable estoppel, or by legal estoppel. The Federal Circuit notes that the different ways in which implied licenses can arise "describe not different kinds of licenses, but rather different categories of conduct which lead to the same conclusion: an implied license." Id. This Court has previously stated that, to prevail on an implied license defense,

> the alleged infringer must show both that the device sold by the patentee has no reasonable, non-infringing use, and that "the circumstances plainly indicate that the grant of a license should be inferred." This second requirement will be met when the elements of equitable estoppel are satisfied. In other words, if the patentee's actions lead the alleged infringer to believe that it has a license to use the invention and, in reliance on those actions, the alleged infringer practices the patent, the court may determine that the patentee's actions created an implied license.

LG Electronics, Inc. v. Asustek Computer, Inc., 2002 WL 31996860, *13 (N.D. Cal.) (citations omitted; quoting Bandag, Inc. v. Al Bolser's Tire Stores, Inc., 750 F.2d 903, 925 (Fed. Cir. 1984)).

Defendant responds that the cases Plaintiff cites discuss implied licenses as a defense to patent infringement charges, not as a defense to anti-trust charges. Plaintiffs do not cite a case holding that an implied license eliminates patent immunity. Nor does Defendant cite a case holding that an implied license cannot eliminate patent immunity under anti-trust laws. In the absence of cited authority, the Court finds that an implied license can eliminate patent immunity under anti-trust laws. If Defendant has impliedly licensed Norvir's use as a booster, then it has waived its right to exclude others from using Norvir as a booster, and cannot rely on its patents to immunize its conduct from anti-trust scrutiny.

Plaintiffs provide evidence that Defendant is aware that patients use Norvir with other PIs to treat HIV and that, by its conduct, Defendant approves and encourages such use. Defendant knows that Norvir is now used almost exclusively as booster for other PIs. Mr. Jesus Leal, Defendant's former general manager, stated that "the company basically finally said" that Norvir "is not a stand-alone PI anymore, this PI is a straight booster." First Weibe Dec., Ex. H at 23:25-26:2. One-hundred milligrams of Norvir is the most commonly used boosting dosage; Defendant markets Norvir as a 100 milligram tablet in a thirty-pill bottle, which Plaintiffs note reflects the fact that many health plans permit a patient to obtain only a thirty-day supply of a drug at one time.

Previously, Norvir was sold in a 120-pill bottle.

Defendant states that it protects its patent rights and has not given anyone an implied license to Norvir's boosting use. But Defendant's own words show otherwise. As Defendant stated in a June 4, 2004 letter to the Federal Trade Commission, "Despite having a right to do so, Abbott did not exclude anybody from taking advantage of ritonavir's boosting properties without buying Kaletra. Instead, Abbott has continued to allow others access to ritonavir's boosting properties by keeping Norvir on the market, even to competitors who refuse to pay a license and encourage the infringement of the patent." First Weibe Dec., Ex. B at NOR 91660 (citation omitted). Defendant notes that five of its competitors have obtained licenses, and contends that patients who buy PIs from those five competitors have the benefit of its express license agreements. Defendant's expert, Hon. Gerald J. Mossinghoff, contends that these license agreements show that Defendant has been protective of its intellectual property rights. At the hearing, Plaintiffs disagreed, arguing that the licenses, which are not in the record, prohibit sublicensing and do not expressly authorize patients to use Norvir as a booster.

Defendant also argues that Plaintiffs' implied license argument fails because they cannot show that there are no non-infringing uses for Norvir; some patients still use Norvir as a stand alone drug. See Glass Equip. Dev., Inc. v. Besten, Inc., 174 F.3d 1337, 1343 (Fed. Cir. 1999). Those patients, however, are few, and likely would not be using Defendant's thirty-pill bottle.

There is a dispute as to whether Defendant has impliedly

licensed Norvir. This is an additional reason to deny Defendant's motion for summary judgment.

3. Anticipation and Obviousness

Plaintiffs also argue that Defendant's immunity defense fails because the '157 patent is invalid. Plaintiff argue that the '157 patent is anticipated by Defendant's '882 and '558 patents, and is obvious. Anticipation of a patent claim requires that a prior art reference "disclose every limitation of the claimed invention, either explicitly or inherently." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999). The Federal Circuit has instructed that

> a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

Id. at 1347.

A patent is invalid for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a). To determine if a patent is invalid for obviousness, the court must consider the scope and content of the prior art, the difference between the patented invention and the prior art, and the level of

skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966); see also Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002). "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998).

Plaintiffs contend that the '882 and '558 patents disclosed the use of Norvir with other PIs to treat HIV, and that the use of Norvir with other PIs to treat HIV was obvious under the prior art. The '882 and '558 patents both state, "Other antiviral agents to be administered in combination with [Norvir] include . . . retroviral protease inhibitors (for example HIV protease inhibitors . . . ."). Second Weibe Dec., Exs. L ('558 patent at 107:67 to 108:10); M ('882 patent at 110:14-25). Claim 1 of the '882 patent states: "A method of inhibiting an HIV infection comprising administering to a human in need thereof a therapeutically effective amount of [Norvir] or a pharmaceutically acceptable salt thereof in combination with a therapeutically effective amount of another HIV protease inhibiting compound." Id., Ex. L at 112:21-29. According to Plaintiffs, inherent in the use of Norvir with other PIs disclosed in these patents is the interaction of Norvir with cytochrome P450 monooxygenase and the resulting improved pharmacokinetics that the '157 patent claims. As noted above, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to

the discoverer." Atlas Powder, 190 F.3d at 1347.

Defendant first responds by arguing that it has several patents covering the boosted market and thus, even if the '157 patent is found to be invalid, its other patents would provide anti-trust immunity. But, as noted above, the Court denies Defendant summary judgment that its other patents covered the boosted market. Defendant next argues that the validity of the '157 patent is irrelevant because anti-trust immunity does not retroactively disappear if a patent is later deemed invalid. The First Circuit has held that "a patentee who has a good faith belief in the validity of a patent will not be exposed to antitrust damages even if the patent proves to be invalid." CVD, Inc. v. Raytheon Co., 769 F.2d 842, 850 (1st Cir. 1985). As Plaintiffs note, however, here, they are not seeking retroactive damages for past anti-competitive conduct; instead, they seek injunctive relief for future monopolistic conduct. CVD, Inc. and other cases Defendant cites are inapposite. Because Plaintiffs seek to address future harm, the validity of Defendant's patent is relevant.

Plaintiffs must prove invalidity by clear and convincing evidence. See, e.g., Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005). But, because they are only opposing Defendant's summary judgment motion, they do not need to prove invalidity by clear and convincing evidence in their opposition. Rather, they need to show that there is a dispute of fact and that there are enough facts from which a jury reasonably could find clear and convincing evidence that the '157 was anticipated and/or obvious. Plaintiffs make such a showing. This is an additional

basis for denying Defendant's motion for summary judgment.

II. Plaintiffs' Objections to the Magistrate's Order

In their discussion of the validity of the '157 patent, Plaintiffs note that they have been denied patent validity discovery. Plaintiffs filed an objection to the Magistrate Judge's January 18, 2006 Discovery Order, which denied Plaintiffs' request for discovery regarding the validity of Defendant's patents. Because of the briefing schedule, Plaintiffs had to file their opposition to Defendant's summary judgment motion before this Court could decide the merits of Plaintiffs' objections. Plaintiffs state that the Magistrate Judge viewed this Court's September 12, 2005 order, granting Plaintiffs' Rule 56(f) motion and denying Defendant's motion for summary judgment without prejudice, as susceptible to contrary interpretations. The Magistrate Judge interpreted the Court's order as providing that Plaintiffs were not entitled to discovery regarding patent validity. But the Court's order did not limit discovery; rather, it merely provided a continuance, allowing Plaintiffs additional time for discovery. Plaintiff's objections (Docket No. 177) to the Magistrate Judge's discovery order are sustained.

III. Plaintiffs' State Law Claims

The parties agree that if the anti-trust claims fail, both of Plaintiffs' State law claims fail as well. As discussed above, the anti-trust claims do not fail as a matter of law. Thus, the State law claims for unfair competition and unjust enrichment under section 17200 of the California Business and Professions Code also do not fail as a matter of law.

CONCLUSION

For the foregoing reasons, Defendant's renewed motion for summary judgment motion (Docket No. 167) is DENIED.[2]

IT IS SO ORDERED.

Dated: 7/6/06

CLAUDIA WILKEN
United States District Judge

[2] In addition, Plaintiffs' Motion to Unseal (Docket No. 219) is DENIED. Defendant's Motion for Leave to File Supplemental Material (Docket No. 244) is also DENIED.